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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,139	07/09/2003	Gary R. Epler	eplc0703	2091

23580 7590 11/23/2007
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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	**PAPER NUMBER**
3736	

MAIL DATE	DELIVERY MODE
11/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,139	EPLER, GARY R.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *4 and 6-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 09/06/2007, amended claim(s) 1, 4-9, and 11-19 and withdrawn claim(s) 4 and 6-53 is/are acknowledged. The current rejections of the claim(s) 1-3 and 5 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Election/Restrictions

2. The Examiner notes claim 1 appears to be generic, but that claims 4 and 6-19 remain withdrawn **without** traverse pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention(s) as they appear to claim the subject matter of at least nonelected Figures 2, 6A, 6B, and 8-11.

Claim Objections

3. Claim 1 is objected to because of the following informalities:

- the positive recitation of "a potential adverse drug reaction" in lines 7-8 should apparently read "the potential adverse drug reaction",
- the positive recitation of "a prescribed medical therapy" in line 8 should apparently read "the prescribed medical therapy",
- the positive recitation of "said test" in line 10 should apparently read "a test",

- the positive recitation of "a sample" in line 11 should apparently read "the sample", and
- the positive recitation of "an adverse drug reaction" in line 14 should apparently read "the potential adverse drug reaction".

4. Appropriate correction is required.

5. Claim 2 is objected to because of the following informalities: the positive recitation of "the group" in line 2 should apparently read "a group". Appropriate correction is required.

6. Claim 5 is objected to because of the following informalities: the positive recitation of "an adverse drug reaction" in line 5 should apparently read "the potential adverse drug reaction". Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Millenson (EP 0 717 283 A2) as broadly as claimed.

9. Millenson discloses a diagnostic and directed medication system (100) that is capable of minimizing a potential adverse drug reaction to a prescribed medical therapy, said system comprising:

- a drug metabolism test component (10) comprising a medical sample receiving apparatus (40) having at least a first sample holding pad (50) configured to receive a user's biological sample (column 4 lines 21-54) for determining the presence of one or more predefined drug metabolism markers that are capable of indicating the potential adverse drug reaction to the prescribed medical therapy; and
- a prescription instruction component (120) containing a first instruction that is capable of directing a user to obtain said drug metabolism test component and to follow the test component instructions to submit the sample for testing (column 5 lines 15-42), and a second instruction that is capable of directing said user on how to obtain a customized medical therapy containing a prescription for a medication that minimizes the potential for the adverse drug reaction, said customized medical therapy being based on a result of said testing (column 5 lines 15-42), said second instruction further is capable of further directing said user to present said result of said testing to a healthcare provider to obtain said customized medical therapy containing a prescription for a medication that minimizes the potential for an adverse drug reaction (column 5 lines 15-42).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millenson in view of Zwanziger et al. (WO 95/33996, hereinafter Zwanziger).

12. Millenson discloses the claimed diagnostic and directed medication system as set forth above, but does not expressly teach the one or more predefined drug metabolism markers being DNA or enzymes or the drug metabolism test component being a genomics-based test. Zwanziger teaches a diagnostic and directed medication system, wherein the one or more predefined drug metabolism markers are DNA or enzymes (page 7 line 3 – page 9 line 20) and the drug metabolism test component is a genomics-based test (page 7 line 3 – page 9 line 20). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Millenson and Zwanziger. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Millenson with the components as taught by Zwanziger to achieve the predictable results of providing alternate diagnostic testing means in a diagnostic and directed medication system.

Response to Arguments

13. Applicant's arguments with respect to claims 1-3 and 5 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. The following prior art is made of record and not relied upon and is considered pertinent to applicant's disclosure. Moore et al. (US 6,727,073 B1) discloses a diagnostic and directed medication system.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)

272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736